



NDA 20-835/S-020

Procter & Gamble Pharmaceuticals, Inc.
Attention: Katherine McNeil
U.S. Regulatory Affairs
Health Care Research Center
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Ms. McNeil:

Please refer to your supplemental new drug applications (NDA) dated June 24, 2005, received June 27, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actonel (risedronate sodium) Tablets.

This "Changes Being Effected" supplemental new drug application provides for adding information regarding severe musculoskeletal pain, and osteonecrosis of the jaw to the **General** subsection of the **PRECAUTIONS** section, adding information concerning severe musculoskeletal pain to the **ADVERSE REACTIONS** section, and updating the **Information for patients** subsection of the **PRECAUTIONS** section of the package insert, and incorporating text into the patient package insert to reflect the changes made to the package insert..

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 24, 2005.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

David Orloff
9/12/2005 01:48:24 PM